

§ 111.117 What quality control operations are required for equipment, instruments, and controls?

Quality control operations for equipment, instruments, and controls must include:

- (a) Reviewing and approving all processes for calibrating instruments and controls;
- (b) Periodically reviewing all records for calibration of instruments and controls;
- (c) Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment; and
- (d) Reviewing and approving controls to ensure that automated, mechanical, or electronic equipment functions in accordance with its intended use.

§ 111.120 What quality control operations are required for components, packaging, and labels before use in the manufacture of a dietary supplement?

Quality control operations for components, packaging, and labels before use in the manufacture of a dietary supplement must include:

- (a) Reviewing all receiving records for components, packaging, and labels;
- (b) Determining whether all components, packaging, and labels conform to specifications established under § 111.70 (b) and (d);
- (c) Conducting any required material review and making any required disposition decision;
- (d) Approving or rejecting any treatment and in-process adjustments of components, packaging, or labels to make them suitable for use in the manufacture of a dietary supplement; and
- (e) Approving, and releasing from quarantine, all components, packaging, and labels before they are used.

§ 111.123 What quality control operations are required for the master manufacturing record, the batch production record, and manufacturing operations?

(a) Quality control operations for the master manufacturing record, the batch production record, and manufacturing operations must include:

- (1) Reviewing and approving all master manufacturing records and all

modifications to the master manufacturing records;

- (2) Reviewing and approving all batch production-related records;
- (3) Reviewing all monitoring required under subpart E;
- (4) Conducting any required material review and making any required disposition decision;
- (5) Approving or rejecting any reprocessing;
- (6) Determining whether all in-process specifications established in accordance with § 111.70(c) are met;
- (7) Determining whether each finished batch conforms to product specifications established in accordance with § 111.70(e); and
- (8) Approving and releasing, or rejecting, each finished batch for distribution, including any reprocessed finished batch.

(b) Quality control personnel must not approve and release for distribution:

- (1) Any batch of dietary supplement for which any component in the batch does not meet its identity specification;
- (2) Any batch of dietary supplement, including any reprocessed batch, that does not meet all product specifications established in accordance with § 111.70(e);
- (3) Any batch of dietary supplement, including any reprocessed batch, that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act; and
- (4) Any product received from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for which sufficient assurance is not provided to adequately identify the product and to determine that the product is consistent with your purchase order.

§ 111.127 What quality control operations are required for packaging and labeling operations?

Quality control operations for packaging and labeling operations must include:

- (a) Reviewing the results of any visual examination and documentation to